

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Ronald Vogels; Abraham Bout

Serial No.: To be assigned

Filed: June 14, 1999

For: PACKAGING SYSTEMS FOR
HUMAN RECOMBINANT ADENOVIRUS
TO BE USED IN GENE THERAPY

Examiner: To be assigned

Group Art Unit: To be assigned

Attorney Docket No.: 4075US

File Copy

#2
8/22/99

NOTICE OF EXPRESS MAILING

Express Mail Mailing Label Number: EL312578267US

Date of Deposit with USPS: June 14, 1999

Person making Deposit: Jared Turner



INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

//In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents are enclosed pursuant to 37 C.F.R. § 1.98(a).

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability

as defined in 37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56(b) exists.

DOCUMENTS

U.S. Patent Documents

	<u>U.S. Patent No.</u>	<u>Issue Date</u>	<u>Inventor</u>
<i>Z</i>	5,378,618	01/03/95	Sternberg et al.
<i>J</i>	5,545,522	08/13/96	Van Gelder et al.
	5,652,224	07/29/97	Wilson et al.
<i>U</i>	5,670,488	09/23/97	Gregory et al.
	5,707,618	01/13/98	Armentano et al.
<i>OC</i>	5,753,500	05/19/98	Shenk et al.

Foreign Patent Documents

	<u>Document No.</u>	<u>Date</u>	<u>Country</u>
<i>N</i>	WO 94/12649 .	06/09/94	PCT
	WO 94/23582 .	10/27/94	PCT
	WO 94/26914 .	11/24/94	PCT
	WO 95/00655 .	01/05/95	PCT
	95201611.1 .	06/15/95	EP
	WO 95/02697 .	01/26/95	PCT
	95201728.3 .	06/26/95	EP
	WO 95/27071 .	10/12/95	PCT
	WO 96/16676 .	06/06/96	PCT
	WO 96/18418 .	06/20/96	PCT
	WO 96/33280 .	10/24/96	PCT
	WO 96/40955 .	12/19/96	PCT
	WO 97/00326 .	01/03/97	PCT
	WO 97/00947 .	01/09/97	PCT
<i>OC</i>	WO 97/04119 .	02/06/97	PCT

R WO 97/05255

02/13/97

PCT

Other Documents

Amalfitano et al., "Improved adenovirus packaging cell lines to support the growth of replication-defective gene-delivery vectors", Proc. Natl. Acad. Sci. USA, 93:3352-3356, April 1996.

Amalfitano et al., "Isolation and characterization of packaging cell lines that coexpress the adenovirus E1, DNA polymerase, and preterminal proteins: implications for gene therapy", Gene Therapy, 4:258-263, 1997.

Armentano et al., "Characterization of an Adenovirus Gene Transfer Vector Containing an E4 Deletion", Human Gene Therapy, 6:1343-1353, October 1995.

Blase et al., "Vectors in Cancer therapy: how will they deliver?", Cancer Gene Therapy, Vol. 2, No. 4, 1995, pp. 291-297.

Bout et al., "In vivo adenovirus-mediated transfer of human CFTR cDNA to Rhesus monkey airway epithelium: efficacy, toxicity and safety", Gene Therapy 1, pp. 385-394, 1994.

Bout et al., "Lung Gene Therapy: In Vivo Adenovirus-Mediated Gene Transfer to Rhesus Monkey Airway Epithelium", Human Gene Therapy, 5:3-10, 1994.

Brough et al., "A Gene Transfer Vector-Cell Line System for Complete Functional Complementation of Adenovirus Early Regions E1 and E4", Journal of Virology, 70(9):6497-6501, September 1996.

Brough et al., "Stable Cell Lines for Complementation of Adenovirus Early Regions E1, E2A and E4; Abstract Book CSH Conference On Gene Therapy, 42, 1996.

Brough et al., "Construction, Characterization, and Utilization of Cell Lines Which Inducibly Express the Adenovirus DNA-Binding Protein", Virology, 190:624-634, 1992.

Caravokyri et al., "Constitutive Episomal Expression of Polypeptide IX (pIX) in a 293-Based Cell Line Complements the Deficiency of pIX Mutant Adenovirus Type 5", Journal of Virology, 69(11):6627-6633, November 1995.

g Fallaux et al., "Characterization of 911: A New Helper Cell Line for the Titration and Propagation of Early Region 1-Deleted Adenoviral Vectors", Human Gene Therapy, 7:215-222, 1996.

Fallaux et al., "New Helper Cells and Matched Early Region 1-Deleted Adenovirus Vectors Prevent Generation of Replication-Competent Adeoviruses", Human Gene Therapy, 9:1909-1917, September 1, 1998.

Fisher et al., "Recombinant Adenovirus Deleted of All Viral Genes for Gene Therapy of Cystic Fibrosis", Virology, 217:11-22, 1996.

Gao et al., "Biology of Adenovirus Vectors with E1 and E4 Deletions for Liver-Directed Gene Therapy", Journal of Virology, 70(12):8934-8943, December 1996.

Gorziglia et al., "Elimination of both E1 and E2a from Adenovirus Vectors Further Improves Prospects for In Vivo Human Gene Therapy", Journal of Virology, 70(6):4173-4178, June 1996.

Haddada et al., "Adenoviral Interleukin-2 Gene Transfer into P815 Tumor Cells Abrogates Tumorigenicity and Induces Antitumoral Immunity in Mice", Human Gene Therapy, 4:703-711, 1993.

Hardy et al., "Construction of Adenovirus Vectors through Cre-lox Recombination", Journal of Virology, 71(3):1842-1849, March 1997.

Hehir et al., "Molecular Characterization of Replication-Competent Variants of Adenovirus Vectors and Genome Modifications To Prevent Their Occurrence", Journal of Virology, 70(12):8459-8467, December 1996.

Imler et al., "Novel complementation cell lines derived from human lung carcinoma A549 cells support the growth of E1-deleted adenovirus vectors", Gene Therapy, 3:75-84, 1996.

Kornberg, Arthur, "DNA Replication", W.H. Freeman and Company, San Francisco, 4 pages (double sided).

g Krougliak et al., "Development of Cell Lines Capable of Complementing E1, E4, and Protein IX Defective Adenovirus Type 5 Mutants", Human Gene Therapy, 6:1575-1586, December 1995.

✓ Lieber et al., "Recombinant Adenoviruses with Large Deletions Generated by Cre-Mediated Excision Exhibit Different Biological Properties Compared with First-Generation Vectors In Vitro and In Vivo", Journal of Virology, 70:8944-8960, December 1996.

Ngo et al., "Computational Complexity, Protein Structure Prediction, and the Levinthal Paradox", The Protein Folding Problem and Tertiary Structure Prediction, 5 pages.

Sabatie et al., "Process Development for the Production of Second Generation Adenovirus Vectors for Gene Transfer in Clinical Protocols", Abstract Book 14th Meeting on Animal Cell Technology, BI-3, 1996.

Schaack et al., "Adenovirus Type 5 Precursor Terminal Protein-Expressing 293 and HeLa Cell Lines", Journal of Virology, 69(7):4079-4085, July 1995.

Vanhaesebroeck et al., Virology, 176(2), pp. 362-368, June 1990.

Vincent et al., "Herpes Simplex Virus Thymidine Kinase Gene Therapy for Rat Malignant Brain Tumors", Human Gene Therapy 7:197-205, January 20, 1996.

Vincent et al., "Treatment of leptomeningeal metastases in a rat model using a recombinant adenovirus containing the HSV-tk gene", J. Neurosurg., Vol. 85, pp. 648-654, 1996.

Wang et al., "A packaging cell line for propagation of recombinant adenovirus vectors containing two lethal gene-region deletions", Gene Therapy, 2:775-783, 1995.

Yeh et al., "Efficient Dual Transcomplementation of Adenovirus E1 and E4 Regions from a 293-Derived Cell Line Expressing a Minimal E4 Functional Unit", Journal of Virology, 70(1):559-565, January 1996.

✓ Zhou et al., "Development of a Complementing Cell Line and a System for Construction of Adenovirus Vectors with E1 and E2a Deleted", Journal of Virology, 70(1):7030-7038, October 1996.

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56 & 1.175, applicant hereby identifies the following listed copending applications naming the same inventor:

Serial No.: 08/515,495

Filed: August 15, 1995

For: RECOMBINANT VECTORS DERIVED FROM ADENOVIRUS FOR USE IN GENE THERAPY

Serial No.: 08/793,170

Filed: March 25, 1997

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS
TO BE USED IN GENE THERAPY

Serial No.: 08/892,873

Filed: July 15, 1997

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS
TO BE USED IN GENE THERAPY

Serial No.: 08/930,094

Filed: December 15, 1997

For: RECOMBINANT VECTORS DERIVED FROM ADENOVIRUS FOR USE IN
GENE THERAPY

Serial No.: 09/065,752

Filed: April 24, 1998

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS
TO BE USED IN GENE THERAPY

Serial No.: 09/097,239

Filed: June 12, 1998

For: HIGH THROUGHPUT SCREENING OF GENE FUNCTION USING AV
LIBRARIES FOR FUNCTIONAL GENOMICS APPLICATIONS

Serial No.: 09/298,745

Filed: April 23, 1999

For: MEANS AND METHODS FOR NUCLEIC ACID DELIVERY VEHICLE
DESIGN AND NUCLEIC ACID TRANSFER

Serial No.: 09/315,244

Filed: May 20, 1999

For: DISPLAY OF VIRAL PROTEINS

Serial No.: 09/315,926

Filed: May 20, 1999

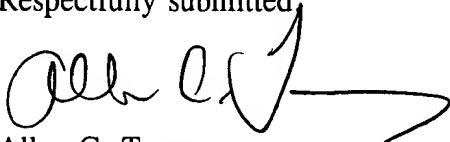
For: TARGETED DELIVERY THROUGH A CATIONIC AMINO ACID
TRANSPORTER

Considered: David Yuz

Applicants offer to supply any explanation or discussion of the documents which the
Examiner feels is necessary or desirable and which is requested.

This Information Disclosure Statement is filed within three (3) months of the filing date of the above-identified application, and no certification pursuant to 37 C.F.R. § 1.97(c) or a fee pursuant to 37 C.F.R. 1.17(p) is required.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Allen C. Turner', with a long horizontal flourish extending to the right.

Allen C. Turner
Registration No. 33,041
Attorney for Applicants
TRASK, BRITT & ROSSA
P. O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: (801) 532-1922

Date: June 14, 1999

ACT/le

Enclosures: Form PTO-1449

Copy of documents cited